## UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE	§	MDL NO. 2342
HYDROCHLORIDE) PRODUCTS	§	
LIABILITY LITIGATION	§	12-MD-2342
	— §	
THIS DOCUMENT RELATES TO ALL	§	HON. CYNTHIA M. RUFE
ACTIONS	§	

DEFENDANTS' MEMORANDUM OF LAW
IN OPPOSITION TO PSC'S MOTION FOR LEAVE TO IDENTIFY
AND PRESENT A NEW GENERAL CAUSATION EXPERT AND POSITION
ON VOLUNTARY DISMISSAL OF CERTAIN CASES WITHOUT PREJUDICE

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Defendants respectfully submit this memorandum in opposition to Plaintiffs' motion to present a new general causation expert and position on voluntary dismissal without prejudice.

### **PRELIMINARY STATEMENT**

Plaintiffs chose when to file their suits, and their lawyers chose which experts they wanted to produce on the issue of general causation - an essential element of their cases. If those choices were successful, Plaintiffs undoubtedly would expect this Court to treat its Daubert decisions as final and binding. Because Plaintiffs lost on Daubert and their experts' opinions on human causation were stricken, Plaintiffs ask this Court for a do-over. They now want to submit a new expert long after the deadline for naming experts expired and well after they had every opportunity, culminating in a seven-day *Daubert* hearing, to present their best expert case on general causation. They also plan to ask to be allowed to dismiss certain cases without prejudice, even though these cases are all bound by the Daubert decisions and are subject to summary judgment dismissal. In short, Plaintiffs are trying to render the exhaustive *Daubert* process, including this Court's decisions, a nullity or a game of "heads-I-win, tails-we-flip-again." Thus, Plaintiffs' effort to revive their claims on the eve of their dismissal with prejudice on summary judgment – either by naming a new expert or dismissing cases without prejudice – would create a completely one-sided form of litigation that is demonstrably unjust. Unsurprisingly, courts have consistently rejected such attempts to skirt finality and fundamental fairness. As the Sixth Circuit cogently noted, allowing the *Daubert* inquiry to be reopened "would be contrary to all rules of fairness and proper procedure." *Pride v. BIC Corp.*, 218 F.3d 566, 579 (6th Cir. 2000).

First, there is no legal basis for allowing Plaintiffs to name a new expert long after the deadline for naming experts. The *Daubert* rulings striking Plaintiffs' causation experts do not justify such a procedure. The parties and the Court poured enormous time and resources into the *Daubert* process. Plaintiffs had a full and fair opportunity to develop and defend their choice of experts. Under well-established case law, Plaintiffs cannot hit the reset button and replace their

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As explained in Defendants' motion for leave to file a motion for summary judgment, filed simultaneously herewith, summary judgment is routinely the next step and is warranted in this matter.

experts at this late stage of the litigation after their causation experts have been stricken.

Second, there is no legal basis for permitting a party to voluntarily dismiss a case without prejudice, after adverse *Daubert* rulings have been rendered, as a means of avoiding dismissal with prejudice on summary judgment. "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (citation omitted). By excluding Plaintiffs' expert causation evidence as unreliable, this Court has found that Plaintiffs have not established an essential element of their claims. No court would allow a minor plaintiff to avoid a final judgment through a voluntary dismissal without prejudice, after a defense verdict based on lack of causation, because the minor plaintiff's claims were subject to statute of limitations tolling until the age of majority. Plaintiffs cannot invoke the statute of limitations as an evergreen mechanism to perpetuate their claims until they reach the age of majority here. To do so perverts the statute of limitations, rules of finality and fairness, and the Federal Rules of Civil Procedure.

Plaintiffs' only available remedy now is an appeal to the Third Circuit from the *Daubert* rulings after the cases are dismissed with prejudice on summary judgment. Plaintiffs' attempts to avoid the only legitimate legal option open to them – appeal – should be rejected by the Court.

### FACTUAL BACKGROUND

In this MDL, Plaintiffs alleged that Zoloft caused all manner of birth defects. In accordance with this Court's Pretrial Orders, Plaintiffs proffered their general causation experts, including Anick Bérard, Ph.D., Thomas Sadler, Ph.D., Robert Cabrera, Ph.D., and Michael Levin, Ph.D. Following full discovery, extensive briefing, and a seven-day *Daubert* hearing, this Court excluded Dr. Bérard's testimony on causation in its entirety, as well as the opinions of Drs. Cabrera, Levin, and Sadler on general causation in humans. (Dkt. [979], [980], [1033], [1034].)

Since the inception of this litigation, Defendants advised this Court that Plaintiffs' causation theories were unsubstantiated and the scientific evidence did not support Plaintiffs' allegations that Zoloft causes birth defects. In view of that scientific reality, Defendants urged

the Court to address the threshold question of general causation as early in the litigation as possible, in an effort to potentially save judicial and party resources. Plaintiffs agreed to stage the proceedings in this MDL such that expert discovery, *Daubert* briefing, and a *Daubert* hearing on general causation would take place ahead of other issues. (*See* PTO 15.) The Court's Pretrial Orders, which were based upon the parties' agreement, provided the parties with a clear and structured roadmap for how expert discovery and motion practice were to proceed, followed by a *Daubert* hearing, and, if appropriate, summary judgment briefing. (*See*, *e.g.*, PTO 23 & 39.) There is no question that these Orders governed and applied to all Plaintiffs in the MDL.

Plaintiffs are represented by some of the most experienced personal injury lawyers in the country, who had ample time and resources, and every incentive, to prepare fully for the *Daubert* proceedings. The Court's Pretrial Orders afforded Plaintiffs a full and fair opportunity to locate, present, develop, and defend their best expert evidence on general causation. Seizing upon that opportunity, Plaintiffs did precisely that. At the *Daubert* hearing, Plaintiffs' attorneys time and again proclaimed that "each and every one" of their experts "have dedicated their professional life to trying to find the cause of and the cure for birth defects." 4/7/14 Tr. at 60:9-19. Plaintiffs avowed that they were "pleased to say that – the God's honest truth this is the best group of experts I have ever seen in one place on one subject in a courtroom in my entire career. These four experts, each and every one of them, are uniquely independently qualified to speak about the issues in this case and whether or not SSRIs and Zoloft cause birth defects." *Id.* at 68:6-13.

The *Daubert* process is now complete and the Court has made its findings: Plaintiffs' experts' general causation opinions are unreliable and inadmissible under Fed. R. Evid. 702. "The best group of experts" that Plaintiffs "have ever" assembled has now been excluded from offering opinions on causation in humans. A review of the entire body of scientific evidence, as required by a sound scientific methodology, reveals that there are no consistent, repeated human epidemiological studies showing a statistically significant increased risk of birth defects associated with Zoloft. As this Court recognized in excluding Dr. Bérard's opinions, "Dr. Bérard is only able to present an illusion of "consistency" because she selectively cites only

findings that (she says) support her opinions." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.* (*Zoloft I*), 2014 WL 2921648, at \*11 (E.D. Pa. June 27, 2014) (citation omitted). In excluding the opinions of Drs. Cabrera, Levin, and Sadler, this Court stated that it "is premature to draw conclusions about human causation from the evidence relied upon by these experts" and that their "opinions about human causation require speculative leaps which are unacceptable in science and in the courthouse." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.* (*Zoloft II*), 2014 WL 3943916, at \*13 (E.D. Pa. Aug. 12, 2014).

#### **ARGUMENT**

# I. PLAINTIFFS PRESENTED "THEIR BEST EXPERT EVIDENCE" AND ARE NOT ENTITLED TO REOPEN THE *DAUBERT* INQUIRY

The *Daubert* process in this case – which involved expert reports, expert depositions, multiple rounds of *Daubert* briefing, and a seven-day *Daubert* hearing – was not a dress rehearsal for the parties. It was the real deal. Plaintiffs are not entitled to a *Daubert* do-over, which would restart the exacting *Daubert* process anew and unfairly prejudice Defendants.

## A. There Is No Legal Basis For Allowing Plaintiffs To Introduce An Untimely Expert Solely Based On Adverse *Daubert* Rulings

Plaintiffs argue that this Court has discretion to amend the scheduling order to allow a new expert under Federal Rule of Civil Procedure 16(b)(4), but that rule allows modifications only "for good cause and with the judge's consent." Plaintiffs simply ignore the "good cause" requirement. Good cause cannot exist where the party provides no justification for failing to comply with the schedule in the first place. Plaintiffs present no explanation for why they failed to present their newly-minted expert, Dr. Jewell – who is long-known to members of the PSC – at the time mandated by the agreed-upon schedule. Nor do they explain why they withdrew their previously-named expert who also opined on epidemiology, Dr. Michel Jean-Jacques Vekemans. Plaintiffs' only suggestion of "good cause" seems to be that, without a new expert, they will lose this case. *See* Pls.' Br. (Dkt. [1054-1]) at 13. That fact is not enough to justify having this Court treat the enormous time and expense of the *Daubert* hearing as a practice run. When a party

loses, the legitimate remedy provided by the Federal Rules is an appeal after a final judgment is entered. But Plaintiffs want to avoid an appeal, presumably because they know the Court's *Daubert* decision here is well reasoned and supported by the applicable law in this Circuit.

Under Supreme Court, Third Circuit, and other federal authority, Plaintiffs are not now entitled to replace their experts based on the belief that they can identify another expert who might offer a reliable opinion. The Supreme Court has held that, "[s]ince *Daubert*, ... parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet. It is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000) (citations omitted). Plaintiffs here seek precisely the "second try" that the Supreme Court found "implausible" in a post-*Daubert* world.

The Third Circuit has unambiguously and repeatedly held that Plaintiffs are not entitled to "an open-ended and never-ending opportunity to meet a *Daubert* challenge." *In re TMI Litig.*, 199 F.3d 158, 159 (3d Cir. 2000), *amending*, 193 F.3d 613 (3d Cir. 2000); *accord Oddi v. Ford Motor Co.*, 234 F.3d 136, 154 (3d Cir. 2000). *TMI* is directly on point. In *TMI*, more than 2,000 plaintiffs alleged they developed neoplasms due to radiation from the Three Mile Island reactor accident. 193 F.3d at 622. "[T]he trial plaintiffs were certainly given the 'opportunity to be heard' in defense of their expert submissions," 199 F.3d at 159, and the district court thus rejected untimely additions to the plaintiffs' expert submissions, 193 F.3d at 717-18. The court excluded most of the expert testimony under *Daubert*, and granted summary judgment for failure to prove causation. *Id.* at 623. The Third Circuit affirmed, rejecting the argument that "a plaintiff must be given the opportunity to meet a *Daubert* challenge with an expert's submission that is based on a new methodology completely different from the one the expert originally engaged in." 199 F.3d at 159. This is exactly what Plaintiffs are attempting to do here.

Plaintiffs attempt to distinguish *TMI* because the court found bad faith based on repeated delays. Pls.' Br. at 10-11 n.13. To be sure, the precise situation in *TMI* was different, but the situation here actually creates a much *stronger* case for exclusion. In *TMI*, the plaintiffs' late-

filed expert reports still came *before* a *Daubert* ruling. Here, in contrast, Plaintiffs are late not due to lack of diligence but because they waited to see how the *Daubert* rulings came out before attempting to add a new expert. Thus, the reasoning of *TMI* – that plaintiffs should not get an open-ended opportunity to satisfy *Daubert* – applies with even greater force here. Other Third Circuit cases also recognize that courts properly "deny a party's motion to add experts ... after a deadline in a scheduling order." *Eichorn v. AT&T Corp.*, 484 F.3d 644, 650-51 (3d Cir. 2007); *see also Coal. to Save Our Children v. State Bd. of Educ.*, 90 F.3d 752, 776 (3d Cir. 1996).

In particular, a new expert is improper where the party provides no legitimate excuse for its failure to meet the deadline. "[A] party asserting that it could not designate an expert witness within the time prescribed by the district court 'has an obligation to provide the court with a record which affirmatively demonstrates, with specificity, diligent efforts on his or her part and unusual circumstances which have frustrated those efforts." *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Litig.*, 85 F. App'x 845, 847 (3d Cir. 2004) (quoting *Koplove v. Ford Motor Co.*, 795 F.2d 15, 18 (3d Cir. 1986)). Where, as here, summary judgment is warranted and plaintiff provides no legitimate excuse for a late expert report, then the report should be rejected. *See id.*; *Steele v. Aramark Corp.*, 535 F. App'x 137, 143 (3d Cir. 2013).

Plaintiffs rely heavily on one Third Circuit case, *ZF Meritor*, *LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), which recognized that "[o]rdinarily, we will not disrupt a district court's decision to deny a party's motion to add information to an expert report under such circumstances. A plaintiff omits evidence necessary to sustain a damages award at its own risk." *Id.* at 297. But there were unique circumstances in that antitrust case, which does not support Plaintiffs' request here. The ruling in *ZF Meritor* came after the court bifurcated liability and damages, and after the plaintiffs "won at the liability stage." *Id.* at 299. With no appealable order, the district court sought to "extract [it]self from the procedural morass" by resurrecting and then denying a "two years old" motion to clarify the expert's calculation on damages. *Id.* at 296-97. With liability already established, that order, which would leave a proven wrong without a remedy, also frustrated "the policy of deterring antitrust violations through the treble

damages remedy." *Id.* at 300. Nor did the defendant "have to analyze any new data, or challenge any new methodologies," *id.* at 298, or respond to a new expert. As the Third Circuit underscored, "Plaintiffs' motion for clarification only sought to include damages calculations based on data already in the expert report, and that fact is *crucial* to our holding that prejudice to [defendant] can be easily cured. *Nothing* in our opinion should be read as requiring the District Court to allow Plaintiffs to bring in entirely new data for the revised damages estimates." *Id.* at 300 n.28 (emphases added). Here, in contrast, Plaintiffs seek to introduce an entirely new expert with a purportedly new methodology, not a "clarification" of a prior expert report.

Similarly, Plaintiffs' reliance on *In re Paoli R.R. PCB Litig.* (*Paoli II*), 35 F.3d 717 (3d Cir. 1994), is unavailing. *Paoli II* also concerned a revised report – not a new expert with a new report, let alone one in response to an adverse *Daubert* ruling – and the court recognized that the usual rule was exclusion. *Id.* at 791-92. The usual rule did not apply due to the particular circumstances, where "there was only a slight deviation from pre-trial notice requirements" and the defendants "were already aware of the basic substance of the witness' testimony" by the deadline. *Id.* The Third Circuit has repeatedly distinguished *Paoli II* on these grounds. *TMI*, 193 F.3d at 722; *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 721 n.10 (3d Cir. 1997).<sup>2</sup>

Other circuit courts also routinely reject late expert testimony offered after the party has lost a *Daubert* ruling. The Sixth Circuit has held that "fairness does not require that a plaintiff, whose expert witness testimony has been found inadmissible under *Daubert*, be afforded a second chance to marshal other expert opinions and shore up his case before the court may consider a defendant's motion for summary judgment." *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 249-50 (6th Cir. 2001); *see also Pride*, 218 F.3d at 579. The Seventh Circuit has rejected similar attempts to "reopen discovery after the district court" excluded plaintiffs' experts under *Daubert* because "[t]he litigation process does not include 'a dress rehearsal or practice

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<sup>&</sup>lt;sup>2</sup> Plaintiffs also cite one other Third Circuit case, *DeMarines v. KLM Royal Dutch Airlines*, 580 F.2d 1193 (3d Cir. 1978), but that case likewise did not involve a new expert when the first expert was struck under *Daubert*. Rather, the issue in *DeMarines* was whether an expert could testify at trial to an opinion that was arguably outside his report, but was suggested in a pre-trial order. *See id.* at 1202.

run' for the parties." Winters v. Fru-Con Inc., 498 F.3d 734, 743 (7th Cir. 2007) (citation omitted). The First Circuit has likewise held that "[a] party who knowingly chooses to put all his eggs in one basket is hard-pressed to complain when the basket proves inadequate and the trial court refuses to allow him to substitute a new and previously undisclosed basket for it." Samaan v. St. Joseph Hosp., 670 F.3d 21, 37 (1st Cir. 2012). The Second Circuit has also affirmed a district court's refusal to permit plaintiffs to substitute their experts where they, as Plaintiffs here, "had a full and fair opportunity to develop and defend their choice of experts." Lippe v. Bairnco Corp., 99 F. App'x 274, 280 (2d Cir. 2004). The Eleventh Circuit has held the same, rejecting a new expert after the first was rejected. "[A] litigant's failure to buttress its position because of confidence in the strength of that position is always indulged in at the litigant's own risk." Rink v. Cheminova, Inc., 400 F.3d 1286 (11th Cir. 2005) (citation omitted). Given the "strong language" in the "overwhelming authority" from appellate courts, district courts have accordingly denied plaintiffs' requests to "reincarnate [their] expert proof' after their experts are excluded under Daubert. Nisus Corp. v. Perma-Chink Sys., Inc., 327 F. Supp. 2d 844, 855 (E.D. Tenn. 2003); see also, e.g., Bambarger v. Ameristep, Inc., 2013 WL 6222540, at \*3 (W.D. Va. 2013); Dunhem v. SunTrust Banks, Inc., 2006 U.S. Dist. LEXIS 100790, at \*12 (D. Md. 2006).

Notwithstanding this overwhelming precedent, Plaintiffs assert that "District Courts typically allow the proponent of the evidence to designate a new expert to testify on the same subject," Pls.' Br. at 10, citing just three cases from across the country. These disparate cases are readily distinguishable. In one, the plaintiffs withdrew their expert when they discovered that he was "less than candid about his prior litigation history," and the "Defendant filed its own designation almost two months after its deadline." *Boyd v. S. Energy Homes, Inc.*, 2012 WL 1601317, at \*1-\*2 (S.D. Miss. 2012). In another, the court allowed a new expert only because of "the difficulty which plaintiff faces," given that "there appear to be only a narrow category of experts who are being found to qualified to testify in cases of this nature across the country." *Krueger v. Johnson & Johnson Prof'l, Inc.*, 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001). And in the last, the court concluded "there is no indication here that the defendants made known their

intention to seek to exclude [the first expert's] testimony," and "[t]he plaintiffs therefore did not have the same warning and opportunity to bolster their evidence early in the case as existed in *Weisgram*." *In re Porter McLeod, Inc.*, 196 F.R.D. 389, 391 (D. Colo. 2000). Here, in contrast, Plaintiffs do not suggest that their original experts were untruthful, that the new expert was hard to find, or that they lacked warning that their experts would be challenged. The *only* reason Plaintiffs provide for designating a new expert is that their original experts were stricken, and Plaintiffs identify no court holding that this reason alone suffices to allow them to name a new expert who allegedly espouses a different methodology than their previous experts.

Plaintiffs' argument conflicts not only with all of the applicable case law, but also with the crucial interests of fairness and finality, as all parties proceeded on the understanding that they should produce their best experts and make their best arguments, and that the *Daubert* ruling would be binding and final. Courts have frequently recognized that allowing a party to reopen *Daubert* proceedings after a *Daubert* decision violates principles of fundamental fairness. In rejecting plaintiffs' effort to introduce a new expert after an adverse *Daubert* ruling, the Second Circuit held that "it would be unfair to the defendants to permit the plaintiffs an opportunity to cure their case after having made 'some ill-advised tactical choices.'" *Lippe*, 99 F. App'x at 280. Other courts agree. "Granting a continuance to allow the Plaintiffs another opportunity to produce admissible evidence of damages ... especially after [the Defendant] has notified the Plaintiffs of flaws in their damages model ... and after clearly spending considerable time, thought, and money to defeat it – strikes the Court as extraordinarily unfair." *Gastaldi v. Sunvest Resort Communities*, *LC*, 709 F. Supp. 2d 1284, 1292 (S.D. Fla. 2010).

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Plaintiffs also cite two circuit court cases, both of which are readily distinguishable. In the first, the court expressly stated that the case "presents unique facts," in particular that "Plaintiffs were referred to [the excluded experts] by defendant." *Summers v. Missouri Pac. RR Sys.*, 132 F.3d 599, 605 (10th Cir. 1997). In the second, the court similarly stated that there were "procedural oddities," including that the plaintiff had gotten "an initial favorable *Daubert* ruling" and the plaintiff's "motion for a new scheduling order is that, at the time it was made, there was no longer any impending trial date or pretrial schedule remaining. That schedule had been completely vacated ...." *Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1254, 1256 (10th Cir. 2011). Here, there are no such unique circumstances.

# B. The Multi-Factor Test For Evaluating Whether To Modify A Schedule Establishes That Doing So Here Would Be Improper And Unfair To Defendants

Plaintiffs point to the five-factor test discussed in *ZF Meritor* for the exclusion of evidence as a discovery sanction, which examines: (1) prejudice to the opposing party; (2) ability to cure the prejudice; (3) disruption of the case; (4) bad faith or willful failure to comply with the court's order; and (5) importance of the excluded evidence. 696 F.3d at 298. As discussed above, there is a basic requirement of good cause in Rule 16(b)(4) that courts consistently find lacking in cases where, as here, Plaintiffs' only basis for a new expert is that their previously named experts were stricken under *Daubert*. In any event, application of the five-factor test here demonstrates that Plaintiffs' motion should be denied.

First, there is significant prejudice to Defendants because they spent an enormous amount of time, effort, and resources opposing Plaintiffs' experts, on the assurance that there would be one *Daubert* hearing on general causation and whatever the outcome, that decision would be binding on all parties. Courts have consistently refused to allow plaintiffs to substitute their experts where, as here, considerable resources have been poured into the proceedings and where defendants would be forced to "invest more time and effort to determine the reliability of [a] newly designated expert, reviewing a second Rule 26 report, deposing the new expert, and perhaps having to file and defend a second Daubert motion." McCool v. Bridgestone/Firestone N. Am. Tire, LLC, 222 F. App'x 847, 856 (11th Cir. 2007); see also Lippe, 99 F. App'x at 280. So, too, here. Plaintiffs initially submitted six general causation expert reports, totaling more than 185 pages. In turn, Defendants prepared eight general causation experts who authored reports and responded to Plaintiffs' experts. Defendants prepared for the depositions of experts, only to have Plaintiffs withdraw three of them before their Plaintiffs' depositions. Plaintiffs' four remaining experts were then deposed, and Defendants prepared a full round of motions to exclude them. The parties then prepared for and participated in a sevenday Daubert hearing, which involved live testimony from all of Plaintiffs' experts and two of Defendants' experts. Other courts were invited to, and did, participate in the hearing. Another round of post-hearing briefing was then prepared and submitted. In turn, this Court devoted substantial time and effort to addressing the issues, as evinced by its thoughtful *Daubert* opinions. Having lost, Plaintiffs now seek to render those exhaustive proceedings a nullity.

*Second*, Plaintiffs do not even argue that they can cure the prejudice to Defendants. Indeed, it would be impossible to do so given the time and effort Defendants (and this Court) have already spent on the *Daubert* proceedings. Plaintiffs are not entitled to a *Daubert* do-over.

Third, there would be significant disruption of the case because Plaintiffs' motion would require a new round of expert reports, briefing, and hearings. See, e.g., Rink, 400 F.3d at 1296. Moreover, Plaintiffs seek to have this case proceed along two tracks, with a motion for reconsideration of this Court's Daubert rulings along with the additional Daubert process for their new expert. Pls.' Br. at 5 n.6. If Plaintiffs believe they have a valid motion for reconsideration, which Defendants do not believe they have, the better course is to let Plaintiffs address this Court's Daubert rulings with respect to Dr. Bérard. Since Plaintiffs assert they have "good arguments to advance" on appeal, id. at 6, they should proceed to an appeal. Moreover, while Plaintiffs argue that because no case is currently scheduled for trial, there would be minimal disruption to the Court's schedule, id. at 12, Plaintiffs' argument relies on the erroneous assumption that the next step in these cases is a trial, when in fact the next step is summary judgment and dismissal of all cases for failure to prove general causation. In addition, while Plaintiffs' motion is supposedly limited to a new expert on cardiovascular defects, Plaintiffs may be hedging their bets. Dr. Jewell suggests that he has "been asked to focus his causation analysis on cardiovascular birth defects" because he "understand[s] that these defects are the focus of the first cases to move forward in the Zoloft litigation." *Id.*, Ex. A at 3.

Fourth, Plaintiffs acted in bad faith because they provide no basis for failing to name Dr. Jewell – who is long-known to members of the PSC – as an expert by the agreed-upon deadline. This litigation has been pending for years and Plaintiffs had more than ample time to develop their general causation expert evidence. Notably, Plaintiffs knowingly waived their opportunity to prepare rebuttal reports to respond to the methodological flaws that Defendants' experts

identified in Plaintiffs' experts' opinions. Plaintiffs then withdrew Dr. Vekemans, who was Plaintiffs' only medical doctor and who also proffered opinions on epidemiology, just two days before his deposition. Moreover, in objecting to Defendants' motion to submit supplemental authority after the *Daubert* hearing, Plaintiffs characterized Defendants' motion as a "request to effectively reopen the record" and asked the Court to deny the motion because the *Daubert* record was "closed." (Pls.' Obj. at 1, [974].) The Court denied Defendants' motion. ([978] at 1.) Plaintiffs' decision to oppose Defendants' effort to add even a supplemental authority, while waiting to see the result of the *Daubert* decisions before adding their own new expert with a purportedly new methodology, establishes Plaintiffs' willful disregard of the deadline.<sup>4</sup>

*Fifth*, the expert report (if accepted) would be important to Plaintiffs' case, but as discussed above, that fact alone does not excuse a failure to bring it at the proper time, with no justification, when Plaintiffs had every opportunity to do so.

# II. IT WOULD BE REVERSIBLE ERROR TO ALLOW DISMISSAL WITHOUT PREJUDICE IN THIS CASE

Plaintiffs are not moving to dismiss without prejudice now; they say only that they may do so in the future. Pls.' Br. at 8 n.11. There is no legal basis for dismissals without prejudice here. Indeed, Plaintiffs' wait-and-see approach demonstrates the problem with permitting dismissals without prejudice. Plaintiffs want to know if this Court will allow them to produce a new expert and if this Court will reconsider its *Daubert* rulings before deciding whether to dismiss their claims. In that way, Plaintiffs will avoid any ruling against them even after having every opportunity in the *Daubert* proceeding to put forward their very best experts, but will take

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Plaintiffs argue that their new "approach to epidemiological evaluation of causation eschews reliance on arbitrary statistical significance limits in favor of a more holistic evaluation of the available data." Pls.' Br. at 4 n.4. Of course, any assessment of Dr. Jewell's approach would require a complete report, responsive expert reports, deposition, and a full *Daubert* hearing – a process that is impossible to undertake since Plaintiffs have not furnished "a final report" with "appendices and the like." *Id.* at 8 n.10. But for purposes of this motion, the crucial fact is that Plaintiffs provide no excuse for failing to bring Dr. Jewell as an expert in the first place. In fact, Plaintiffs concede that Dr. Jewell's analysis is "[b]ased largely on the existing studies that were in evidence at the past *Daubert* hearing," and included new studies only "[f]or the sake of completeness." *Id.* at 8 & n.9.

advantage of any ruling in their favor. Courts have consistently rejected this approach as a violation of basic principles of finality and fairness.

### A. Where Summary Judgment Is Warranted, Dismissal Without Prejudice Is Reversible Error

It would be an abuse of discretion for the Court to dismiss Plaintiffs' claims without prejudice under Fed. R. Civ. P. 41(a)(2) because it would unfairly harm Defendants and make pointless all of the proceedings in this case. When faced with a motion for voluntarily dismissal from a plaintiff, a district court "must 'decide the presence or extent of any prejudice to the defendant by the draconian measure of dismissing plaintiff's complaint." Diet Drugs, 85 F. App'x at 847. Relevant factors a court should consider include: (i) the expense of a second litigation, (ii) the effort the defendant has expended, (iii) the extent to which the case has progressed, (iv) the plaintiff's diligence in bringing the motion, and (v) whether a dispositive motion is pending. D.C.G. ex rel. E.M.G. v. Wilson Area Sch. Dist., 2009 WL 838548, at \*3 (E.D. Pa. 2009). Here, all of these factors support rejection of Plaintiffs' attempt to dismiss without prejudice: Defendants have spent enormous resources on this MDL; a second litigation would force Defendants to duplicate this effort in large part; Plaintiffs have shown no diligence in bringing the motion, as they still have not brought it; and the case has progressed to a point where dismissal with prejudice is required. Moreover, in analyzing these factors, courts have uniformly held that dismissal without prejudice is improper where, as here, the plaintiffs are using it to avoid an impending summary judgment ruling.

The Third Circuit's cases would not permit a dismissal without prejudice at this stage in a case – when there has been a definitive *Daubert* decision and Defendants have timely sought to file a motion for summary judgment. In *Ferguson v. Eakle*, 492 F.2d 26, 29 (3d Cir. 1974), the Third Circuit held that the district court abused its discretion in allowing a voluntary dismissal without prejudice where the defendant was harmed by having spent significant resources on the proceedings. Here, as discussed above, the pretrial proceedings have been extensive. Moreover, the harm to Defendants is far more significant than in *Ferguson*, where the merits were still yet

to be decided, since Plaintiffs' claims should be dismissed with prejudice based on the rulings this Court has already made. Similarly, in *Diet Drugs*, when the plaintiff's request to designate a new causation expert was denied by the MDL court, with a summary judgment motion pending, he moved for a voluntary dismissal without prejudice. 85 F. App'x at 846-47. The MDL court denied the plaintiff's motion to dismiss and entered summary judgment. *Id.* at 847. The Third Circuit affirmed the MDL court's decisions. *Id.* at 847-48; *see also, e.g., Hayden v. Westfield Ins. Co.*, 2014 WL 4637987, at \*6 (3d Cir. 2014) (affirming denial of dismissal without prejudice). Indeed, courts have rejected plaintiffs' voluntary dismissal without prejudice simply because the plaintiffs "would not be bound by the discovery already completed in this case," *Rotshteyn v. Klos Const., Inc.*, 2004 WL 503480 (E.D. Pa. 2004), a far less harmful result than what Plaintiffs would achieve by removing the binding effect of the *Daubert* rulings.

Other Circuits have followed the same approach. In *Grover by Grover v. Eli Lilly & Co.*, 33 F.3d 716 (6th Cir. 1994), which involved birth-defect claims filed by minor plaintiffs, the district court allowed voluntary dismissal without prejudice, but the circuit court reversed, finding an abuse of discretion. The Sixth Circuit held that "[a]t the point when the law clearly dictates a result for the defendant, it is unfair to subject him to continued exposure to potential liability by dismissing the case without prejudice." *Id.* at 719. Similarly, the First Circuit has held that "a plaintiff cannot conduct a serious product liability claim in a federal court, provoke over a year's worth of discovery and motion practice, allow the case to reach the stage at which the defendant filed a full-scale summary judgment motion, and then when matters seemed to be going badly for plaintiff simply dismiss its case and begin all over again." *Doe v. Urohealth Systems, Inc.*, 216 F.3d 157, 163 (1st Cir. 2000). Numerous other courts are in accord.<sup>5</sup>

The reason for this uniform precedent is obvious: a plaintiff cannot use voluntary dismissal without prejudice as a means of avoiding an imminent dismissal with prejudice. "If

<sup>&</sup>lt;sup>5</sup> See, e.g., Davis v. USX Corp., 819 F.2d 1270, 1274 (4th Cir. 1987); In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., 2012 WL 3290145 (E.D. Ky. 2012), aff'd, 2014 WL 2959271 (6th Cir. 2014); In re Fed. Nat'l Mortgage Ass'n Secs., Deriv., & "ERISA" Litig., 725 F. Supp. 2d 169, 178 (D.D.C. 2010).

Plaintiffs are attempting to withdraw their Complaint to avoid an adverse determination on Defendants' motion for summary judgment, the Court is certainly not inclined to grant Plaintiffs' request." *D.C.G.*, 2009 WL 838548, at \*4. Rather, Rule 41(a)(2) should be enforced to "prevent[] plaintiffs from litigating, losing, and then wiping the slate clean by voluntarily dismissing their action." *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 177 (4th Cir. 2007). "[I]t is settled that a plaintiff may not obtain a non-prejudicial voluntary dismissal simply to circumvent adverse rulings." *Teck Gen. P'ship v. Crown Cent. Petroleum Corp.*, 28 F. Supp. 2d 989, 991-92 (E.D. Va. 1998). Here, Plaintiffs essentially concede that they will seek voluntary dismissal without prejudice because the *Daubert* rulings have rendered them incapable of proving their claims. *See* Pls.' Br. at 13. Accordingly, the *only* reason for dismissal without prejudice would be precisely the reason that courts have found improper and illegitimate.

Plaintiffs argue they have diligently pursed dismissal because "these papers" were filed soon after the *Daubert* decisions, Pls.' Br. at 17, but "these papers" do not seek dismissal without prejudice. They simply discuss the issue while leaving open when and in what cases they will seek dismissal without prejudice. Moreover, waiting until after an adverse ruling that would lead to dismissal with prejudice does not show diligence. Rather, it reveals a tactical decision to try to get the benefit of a favorable ruling while avoiding the binding effect of a negative one.

Plaintiffs also argue that case-specific discovery has occurred only in the 25 Initial Discovery Pool cases, Pls.' Br. at 17, but the *Daubert* briefing, hearing, and decisions apply to all the pending cases. As discussed above, there has been an enormous amount of effort brought to bear on the *Daubert* issues, as well as the extensive discovery outside of the *Daubert* context.<sup>6</sup>

Finally, Plaintiffs argue that "it hardly seems fair to bar any tort recovery by the relative handful of children who have already sued while leaving the hundreds of potential claimants who have not yet sued free to do so in the future," Pls.' Br. at 18, but Plaintiffs ignore the fact that the

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Defendants began responding to Plaintiffs' discovery requests in August 2012 and have to date produced over 3.3 million pages. Defendants also prepared and produced 19 witnesses for 30(b)(6) and fact depositions; litigated at least 25 discovery motions submitted to the Special Discovery Master; and prepared for and took 80 depositions of Plaintiffs and other fact witnesses in the Discovery Group cases.

people who sued here made that choice. That choice came with the potential benefit of receiving a favorable judgment, something that the people who have not yet sued would not receive. There is unfairness only if Plaintiffs are allowed to win a lawsuit, while facing no risk of losing.<sup>7</sup>

### B. The Possibility That Science Might Change Does Not Allow A Plaintiff To Dismiss Without Prejudice

Plaintiffs elected to bring their lawsuits when they did. They cannot now avoid summary judgment by relying upon their mere conjecture that the science might change sometime in the future. First, as a factual matter, there is no legitimate reason to think that the science will change. Plaintiffs note that there is "intense scientific interest in [Zoloft's] potential teratogenic effects," Pls.' Br. at 7, but there has been such interest for decades, and the science still does not support the conclusion that Zoloft causes birth defects. *See Zoloft II*, 2014 WL 3943916, at \*9.

Moreover, since the *Daubert* hearing, the science has become even stronger in demonstrating the lack of a causal effect between Zoloft and birth defects.

- ➤ American Heart Association (2014): "[T]here is no increased risk of [congenital heart disease] CHD associated with the use of most SSRIs, although [Paxil] may be an exception."
- ➤ <u>Huybrechts (2014)</u>: "We found no significant associations ... between [Zoloft] and ventricular septal defect." Moreover, "no significantly increased risks were observed with respect to specific cardiac defects."
- ➤ McDonagh (2014): For Zoloft, "[meta-a]nalysis based on the seven studies that reported adjusted odds ratios indicates no increased risk for major malformations." Further, a "[s]ensitivity analysis ... resulted in a pooled estimate suggesting a reduced risk of cardiac anomalies with [Zoloft]."<sup>10</sup>

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<sup>&</sup>lt;sup>7</sup> Plaintiffs suggest that this Court could impose conditions on voluntary dismissal, but these proposed conditions – filing in federal court after some period of time – would do nothing to prevent the harm to Defendants of allowing Plaintiffs to avoid a ruling on the merits when they failed to prove their claims.

<sup>&</sup>lt;sup>8</sup> Donofrio et al., *Diagnosis and Treatment of Fetal Cardiac Disease: A Scientific Statement From the American Heart Association*, 129 Circulation 2183, 2190 (2014), Dkt. [846-2].

<sup>&</sup>lt;sup>9</sup> Huybrechts et al., *Antidepressant Use in Pregnancy and the Risk of Cardiac Defects*, 370 NEJM 2397, 2401-02 (2014), Dkt. [973-2].

McDonagh et al., Antidepressant Treatment of Depression During Pregnancy and the Postpartum Period, Evidence Report/Technology Assessment No. 216, AHRQ Pub. No. 14-E003-EF, at 43, 45 (2014) (attached as Ex. 1).

➤ <u>Jimenez-Solem (2014)</u>: "[T]he present study brings us one step closer to a verdict of not guilty for the SSRIs" as being major teratogenic agents. 11

Second, the possibility that the science could change cannot stand in the way of summary judgment. If that were the case, in every pharmaceutical products case, plaintiffs could argue the science can change in the future and therefore their claims should be dismissed without prejudice to avoid a judgment on the merits. Other courts have clearly rejected such attempts to avoid finality and fairness, and so should this Court.

In *Elkins v. Richardson-Merrell, Inc.*, 842 F. Supp. 996 (M.D. Tenn. 1992), *aff'd*, 8 F.3d 1068 (6th Cir. 1993), it was alleged that the plaintiff minor "was born with severe birth defects because of his mother's ingestion of Bendectin while pregnant." *Id.* at 996. The court entered summary judgment even though the Sixth Circuit "did not rule out the possibility" that at some future date "Bendectin may be proven to cause birth defects in humans." *Id.* More generally, a plaintiff can always claim that evidence might change in the future; if that mere possibility sufficed, a plaintiff could always avoid a judgment on the merits. There is no legal basis for this absurd result. In *Daubert*, which was a birth defect case, the Supreme Court recognized that "[t]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision," whereas the law "must resolve disputes finally and quickly." 509 U.S. at 596-97.

Further, dismissal without prejudice is not the proper remedy for dealing with the possibility of new evidence. There is already a procedure for allowing plaintiffs to use new evidence in certain, limited situations. *See, e.g.*, Fed. R. Civ. P. 60(b); *Jarvis v. Analytical Lab. Servs.*, 499 F. App'x 137, 140 (3d Cir. 2012). The procedure is *not* to allow plaintiffs to file new cases ad infinitum. If Plaintiffs' theory were adopted by the Court, defendants would unjustly remain subject to lawsuits simply on the supposition that a claim might have a factual or scientific basis in the future. Indeed, Plaintiffs' argument would apply beyond summary

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<sup>&</sup>lt;sup>11</sup> Jimenez-Solem, *Exposure to Antidepressants During Pregnancy – Prevalences and Outcomes*, 61 Dan. Med. J. 1, 8 (2014) (attached as Ex. 2).

judgment, even to a decision after a trial, but there is no plausible basis for treating dismissal without prejudice as a way to avoid a merits decision already made or one that should be made. In any event, there is nothing in a dismissal without prejudice that would limit Plaintiffs to only new scientific evidence, rather than simply bringing essentially the same evidence in hopes of a different ruling from a different court.

If Plaintiffs had prevailed in the *Daubert* rulings, the Court surely would not have allowed Defendants to stay the litigation until the minors reached the age of majority, based on the possibility that the science could change in Defendants' favor. Yet there is no basis in law for Plaintiffs' theory to apply only if the change in science benefits them. There may always be changes in science (or other circumstances) that could affect the outcome of a suit if it were brought at a later date, but both sides must take the facts and science as they are when the case is decided. As the Fifth Circuit has held, "the law cannot wait for future scientific investigation and research. We must resolve cases in our courts on the basis of scientific knowledge that is currently available." *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc).

Plaintiffs argue that "[c]ourts have generally held that where a plaintiff's ability to prove a critical element of his or her cause of action depends on events that may occur in the future, it is appropriate to dismiss the litigation without prejudice rather than enter summary judgment." Pls.' Br. at 14-15. But Plaintiffs identify only two cases that supposedly followed this principle, and neither supports Plaintiffs here. Plaintiffs rely on *In re Paoli R.R. PCB Litig.*, 916 F.2d 829 (3d Cir. 1990), but that case did not concern dismissal without prejudice, but amendment of a complaint. *Id.* at 863. Also, the Third Circuit expressly held that the amendment was proper because it concerned only the plaintiffs' theory of damages, not the causation issues that the parties had spent substantial effort litigating. *Id.* Here, the dismissal without prejudice would, in fact, negate the causation ruling that the parties have spent significant resources litigating.

Plaintiffs also rely on *In re Agent Orange Prods. Liab. Litig.*, 603 F. Supp. 239 (E.D.N.Y. 1985), *aff'd in part, rev'd in part on other grounds*, 818 F.2d 194 (2d Cir. 1987), but that case is inapposite for several reasons. First, the plaintiffs in that case moved for voluntary dismissal

before the court's ruling on the causation issues, not (as here) in response to an adverse ruling on general causation. See id. at 242. Second, Agent Orange arose before the Supreme Court changed the landscape for summary judgment, holding that "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case." Celotex, 477 U.S. at 322 (emphasis added). Third, because Agent Orange was also pre-Daubert, it relied on the fact that "plaintiffs' attorneys have done little to advance the case during the many years it has been pending," so "these cases have placed no substantial burden on the government," 603 F. Supp. at 248, in direct contrast to the burden caused by the extensive Daubert proceedings here. Fourth, Agent Orange allowed dismissal without prejudice only for minors, and as discussed below, there is no legal basis for treating the minors' claims differently. Finally, it has been 30 years since Agent Orange, and Plaintiffs fail to cite a single case following its reasoning permitting voluntary dismissal without prejudice.

# C. The Presence Of Minor Plaintiffs Does Not Allow Plaintiffs To Avoid Dismissal With Prejudice

Plaintiffs provide no legal basis for their argument that minors should have a special entitlement to a dismissal without prejudice. It is well established that ""once suit is filed on behalf of a minor child, the parents and guardians are generally subject to the same rules of civil procedure as all other litigants." *Ater v. Follrod*, 238 F. Supp. 2d 928, 948-49 (S.D. Ohio 2002). As discussed in the Restatement, "a judgment for or against a party who lacks capacity is properly given preclusive effect if there has been effective representation of his interests." Restatement (Second) of Judgments § 35, cmt. c. "An infant, when plaintiff, is as much bound and as little privileged as one of full age." *Kingsbury v. Buckner*, 134 U.S. 650, 674 (1890). Indeed, there is nothing in Rule 41, or any other federal rule, allowing for differential treatment of minor plaintiffs for purposes of dismissal.

Minors cannot dismiss claims without prejudice simply because of their status as minors. For instance, in a case almost identical to this one, brought by a minor for an alleged birth defect

caused by a prescription drug, the Sixth Circuit held that the district court "abused its discretion by granting ... dismissal without prejudice." *Grover*, 33 F.3d at 718. "At the point when the law clearly dictates a result for the defendant, it is unfair to subject him to continued exposure to potential liability by dismissing the case without prejudice." *Id.* at 719. In arguing that minors should be treated differently, Plaintiffs cite only one case, *Agent Orange*, but as noted above, it is readily distinguishable. Also, *Agent Orange* identifies no legal basis for its differential treatment of minors, and no court in the three decades since has followed its unsupported approach.

The only justification Plaintiffs provide for treating the minor plaintiffs differently is that they will have tolling of the statute of limitations under various state laws. However, the statute of limitations applies only to the decision to file an action, not what happens after the action is filed. "Statutes of limitations are primarily designed to assure fairness to defendants," *Burnett v. New York Cent. R. Co.*, 380 U.S. 424, 428 (1965), and to "protect defendants from the unfair surprise of stale claims," *Kreiger v. United States*, 539 F.2d 317, 322 (3d Cir. 1976). Thus, statutes of limitation do not, as Plaintiffs erroneously contend, function as safety relief valves that continue to preserve the viability of lawsuits once the merits have been adjudicated. That the statute of limitations may be extended for minors "does not proscribe courts from dismissing such a cause of action with prejudice before the period of limitation has run after the suit has been filed." *Sander v. Dow Chem. Co.*, 651 N.E.2d 1071, 1082-83 (III. 1995). In short, there is no basis in the law or in the policy considerations that require finality and fairness to a defendant to permit minors to file a claim and fail on the merits, but obtain a voluntary dismissal without prejudice so they can take a second try at the claim years down the road before another court.

### **CONCLUSION**

For the foregoing reasons, this Court should deny Plaintiffs' Motion for Leave to Identify and Present a New General Causation Expert.

See also, e.g., Pasteur v. Skevofilax, 914 A.2d 113, 131 (Md. 2007); Madrid v. Nikac, 755 N.Y.S.2d
 379, 379-80 (N.Y. App. Div. 2003); Kubiak v. Robert Wood Univ. Hosp., 753 A.2d 166, 170 (N.J. Super.
 Ct. App. Div. 2000); Altimus v. Hyundai Motor Corp., 578 N.W.2d 409, 411-12 (Minn. App. 1998).

Dated: New York, New York

October 21, 2014

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**CERTIFICATE OF SERVICE** 

I hereby certify that on October 21, 2014, I electronically filed the foregoing with the

Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing

to all CM/ECF participants.

Dated: New York, New York

October 21, 2014

/s/ Mark S. Cheffo Mark S. Cheffo

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